

STATUS OF CLAIMS

Claims 1-20 are pending.

Claims 1-20 stand rejected.

Claims 1-10 and 19 have been amended without prejudice.

REMARKS

Change of Correspondence Address

Applicant submits herewith a Request to change correspondence address. Applicant respectfully requests all correspondence regarding this application be addressed to the address associated with Customer Number 45,722.

Claim Amendments

Applicant has amended Claim 1 to recite, *inter alia*, "an apparatus containing the substance to be delivered and positioned substantially adjacent tissue." Support for such a limitation may be found throughout the application as originally filed, such as at par. [27] ("A TDD may contain, for example, one or more medications for the treatment of disease or relief of pain."). By way of further example, support may also be seen at Fig. 1 and par. [40] ("Referring now to FIG. 1, there is shown an illustration of an embodiment of the present invention as it is placed upon the arm of a patient. An enhanced TDD system may comprise a control device 1, which may be placed directly over a TDD 2. The control device 1, may include an ultrasound sensor. The control device 1 and patch 2 may be attached to the exterior of the patient's skin 3 by means of a strap 4, which may hold the control device 1 and TDD 2 in place.").

Applicant has also amended Claim 1 to recite, *inter alia*, "at least one ultrasonic transducer being sonically coupled to the substance containing apparatus and generating at least one ultrasonic transmission that induces movement of the substance from the substance containing apparatus and into the tissue." Support for this limitation may also be found throughout the application as originally filed, such as at par. [30] ("According to an embodiment of the present invention, a cymbal type transducer or transducer array (flexensional class V) may be used as an ultrasonic sensor device to

deliver either low or high frequency ultrasound transmissions through the TDD for the purpose of functioning as a "fuel gauge" indicator of the drug remaining within the TDD at any point in time.") and at par. [50] ("By way of non-limiting example, the present invention may include an array which may include four transducers, with each transducer transmitting a driving force of 20-30 kHz ultrasonic frequency at 125 mW/sq. cm intensity using an alternating ultrasonic waveform consisting of 100 milliseconds on saw tooth waveform and then 100 milliseconds on square waveform before converting back to sawtooth. The sawtooth waveform component may enlarge skin pores and the square waveform may drive the drug from the patch through the skin.").

Applicant has also amended Claim 1 to recite, *inter alia*, "at least one sensor positioned with said at least one transducer and receiving at least some of the ultrasonic transmissions from said substance containing apparatus." Again, support for such a limitation may be found throughout the original application, such as at par. [27] (*"The sensor, when activated may, by its internal timing circuitry, generate an ultrasonic vibration or sonic transmission through the TDD, causing an echo pattern, which may be received by a transducer receiver."*) and at par. [50] (*"Two of the transducers of the array may then convert to a higher frequency transmission about every 60 seconds. A frequency, 80 kHz, at the same intensity, 125 mW/sq. cm, sends an ultrasonic pulse through the absorbent pad of the patch which may last only 100 milliseconds using a sinusoidal waveform. The pulse may be similar to a sonar transmission and may have both a forward transmission and a return transmission or echo. The echo may then be received by the other two transducers in the array and may produce a voltage which may correspond to the degree of wetness of the liquid content on the absorbent pad."*).

Claim 1 has also been amended to recite, *inter alia*, "wherein, said ultrasonic transmissions received by said at least one sensor are indicative of substance actually liberated from the substance containing apparatus." Again, support for such a limitation may be found throughout the application as originally filed, such as at par. [50] (*"Two of the transducers of the array may then convert to a higher frequency transmission about every 60 seconds. A frequency, 80 kHz, at the same intensity, 125 mW/sq. cm, sends an ultrasonic pulse through the absorbent pad of the patch which may last only 100 milliseconds using a sinusoidal waveform. The pulse may be similar to a sonar*

transmission and may have both a forward transmission and a return transmission or echo. The echo may then be received by the other two transducers in the array and may produce a voltage which may correspond to the degree of wetness of the liquid content on the absorbent pad.”).

Claim 2-10 and 19 have been amended consistently and to improve readability.

Accordingly, no new matter has been presented.

Claim Rejections

Claims 1, 9 and 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis (United States Patent No. 6,392,327) in view of Nagar (United States Patent No. 6,846,288). Claims 10, 18 and 20 apparently stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (United States Patent No. 6,475,148) in view of Nagar.¹ Claim 2 stands rejected under 30 U.S.C. 103(a) as being unpatentably over Lewis in view of Nagar, and further in view of Shimada (United States Patent No. 5,267,985). Claims 3-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis in view of Nagar, and further in view of Dellagatta (United States Patent No. 5,954,675). Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson in view of Nadar, and further in view of Shimada. Claims 12-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson in view of Nadar, further in view of Dellagatta. Applicant requests reconsideration and removal of these rejections for at least the following reasons.

To establish a *prima facie* case of obviousness under 35 U.S.C. 103(a), all of the recited claim limitations must be taught or suggested in the prior art. See, 2143.03 *citing In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (“All words in a claim must be considered in judging the patentability of that claim against the prior art.”) and *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Lewis and Nagar

¹ The April 18, 2007 Office action actually asserts that the rejection is under 102(a) as being anticipated by Jackson in view of Nadar. Should a Notice of Allowance not be forthcoming, Applicant requests clarification of the actual grounds for rejecting Claims 10, 18 and 20.

fail to teach or suggest each of the limitations of any of the rejected claims – and hence fail to render any of these claims unpatentably obvious as a matter of law.

Turning first to Claim 1, it recites:

A substance delivery device, comprising:
an apparatus containing the substance to be delivered and positioned substantially adjacent tissue;
at least one ultrasonic transducer being sonically coupled to the substance containing apparatus and generating at least one ultrasonic transmission that induces movement of the substance from the substance containing apparatus and into the tissue; and
at least one sensor positioned with said at least one transducer and receiving some of the ultrasonic transmissions from said substance containing apparatus;
wherein, said ultrasonic transmissions received by said at least one sensor are indicative of substance actually liberated from the substance containing apparatus.

Thus, Claim 1 broadly calls for a substance delivery device having a substance containing apparatus, an ultrasonic transducer sonically coupled to the apparatus, and a sensor positioned with the transducer such that the sensor receives some of the transducer emissions from the substance containing apparatus, where the received transmissions are indicative of substance delivered from the substance containing apparatus. Applicant submits the cited art fails to teach or suggest such a device.

The primary reference Lewis merely describes a general purpose transducer that includes a feedback mechanism that senses changes in the operational elements of the transducer itself. Lewis does not receive ultrasonic transmissions from any other apparatus, no less a substance containing apparatus. Further, Lewis does not receive ultrasonic transmissions that are indicative of substance actually liberated from a substance containing apparatus. Applicant notes the April 18, 2007 Office action acknowledges this distinction, at least where it asserts, “Lewis discloses the claimed invention except for the a *[sic]* sensor positioned to receive ultrasonic transmissions reflected from the tissue or the substance.” *4/18/2007 Office action, pg. 3, ll. 18-21.*

In an effort to remedy this deficiency of Lewis, the asserted rejections rely upon and incorporate the imaging system of Nagar into Lewis. *See, 4/19/2007 Office action,*

pg. 3, l. 18 – pg. 4, l. 11. Applicant submits Nagar fails to remedy the shortcomings of Lewis though, such that a *prima facie* case of obviousness is lacking.

Nagar also fails to teach or suggest a sensor positioned with a transducer such that the sensor receives some of the transducer emissions from a substance containing apparatus, where the received transmissions are indicative of substance liberated from the substance containing apparatus. Rather, Nagar is concerned with determining the concentration of a substance in a body and for determining the concentration of a substance as a function of position in the body. See, col. 1, ll. 11-15. More particularly, Nagar proposes to locate a blood vessel in a person's body, and then determine the body's glucose level by assaying blood present in the located vessel. See, e.g., col. 2, ll. 28-34.

Thus, and in contrast to Claim 1, nothing in Lewis or Nagar teach or suggest, in any manner what-so-ever, that ultrasonic transmissions that are indicative of substance actually liberated from a substance containing apparatus may be received from a substance containing apparatus by a sensor positioned with a source of the ultrasonic transmissions.

Consistently, Applicant submits Lewis and Nagar fail, in any combination, to teach or suggest each of the limitations of Claim 1, such that a *prima facie* case of obviousness is lacking. Accordingly, Applicant requests reconsideration and removal of the rejection of Claim 1. Applicant also requests reconsideration and removal of the rejections of Claims 2-9 and 19 as well, at least by virtue of these claims' ultimate dependency upon a patentably distinct base Claim 1.

Turning now to Claim 10, it recites:

A method for substance delivery, comprising:
 placing at least one substance substantially adjacent to an external surface of a tissue;
 generating at least one ultrasonic transmission from at least one ultrasonic transducer, wherein the generated at least one ultrasonic transmission induces delivery of said at least one substance through said external surface and into said tissue; and
 sensing reflections of the ultrasonic transmissions from said at least one substance adjacent to the external

surface of the tissue using at least one sensor positioned with the at least one ultrasonic transducer;
wherein, said sensed portion of the ultrasonic transmissions are indicative of substance actually moved into said tissue.

Thus, Claim 10 broadly calls for placing a substance adjacent to a tissue surface, inducing delivery of the substance through the surface and into the tissue by generating ultrasound, and sensing reflections of the ultrasound from the substance adjacent the surface, wherein the sensed reflections are indicative of substance moved into the tissue.

Jackson, like Lewis and Nagar, fails to teach or suggest such a methodology. Instead, Jackson concerns destroying micro-spheres, micro-particles and contrast agents that were previously introduced into a body via physical (e.g., intravenous) injection.

Further, the asserted rejections acknowledge that Jackson fails to teach the recited reflection sensing of Claim 10. *See, e.g., 4/17/2007 Office action, pg. 5, ll. 3-6.* In an effort to remedy this deficiency of Jackson, the asserted rejections again rely upon and incorporate the imaging system of Nagar. *See, 4/19/2007 Office action, pg. 3, l. 18 – pg. 4, l. 11.*

However, as set forth above, Nagar fails to teach or suggest sensing reflections of ultrasound from a substance positioned on an external surface of a tissue. Instead, Nagar proposes to locate a blood vessel in a person's body, and then determine the body's glucose level by assaying blood present in the located vessel. *See, e.g., col. 2, ll. 28-34.*

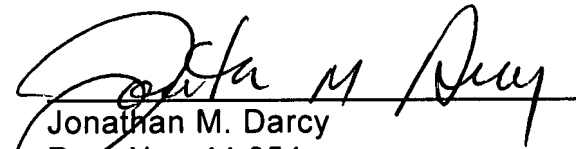
Accordingly, Jackson and Nagar fail, in any combination, to teach or suggest each of the limitations of Claim 10, such that a *prima facie* case of obviousness thereof is also lacking. Accordingly, Applicant requests reconsideration and removal of the rejection of Claim 10. Applicant also requests reconsideration and removal of the rejections of Claims 11-18 and 20 as well, at least by virtue of these claims' ultimate dependency upon a patentably distinct base Claim 10.

CONCLUSION

Wherefore, Applicant believes he has addressed all outstanding grounds raised by the Examiner and respectfully submits the present case is in condition for allowance, early notification of which is earnestly solicited.

Should there be any questions or outstanding matters, the Examiner is cordially invited and requested to contact Applicant's undersigned attorney at his number listed below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jonathan M. Darcy", is written over a horizontal line.

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